UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,117	11/18/2003	Jing Li	006539.00051	6377

22907 7590 04/21/2006

BANNER & WITCOFF
1001 G STREET N W
SUITE 1100
WASHINGTON, DC 20001

EXAMINER	
KAPUSHOC, STEPHEN THOMAS	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,117	LI ET AL.	
	Examiner	Art Unit	
	Stephen Kapushoc	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-134* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-134* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, drawn to methods for cancer diagnosis based on SPHK1 gene copy number, classified in class 435, subclass 6.

II. Claims 4-9, 14-20, drawn to SPHK1 nucleic acid based methods of cancer treatment, classified in class 514, subclass 44.

III. Claims 10-11, drawn to SPHK1 protein inhibition based methods of cancer treatment, classifiable in class 424, subclass 130.1.

IV. Claims 12-13, drawn to methods for cancer diagnosis based on SPHK1 protein level determination, classifiable in class 435, subclass 7.1.

V. Claims 21-32, drawn to SPHK1-based methods for screening a test molecule and determining treatment efficacy, classified in class 436, subclass 501.

VI. Claims 33-35, drawn to methods for cancer diagnosis based on EDG4 gene copy number, classified in class 435, subclass 6.

VII. Claims 36-41, 46-52, drawn to EDG4 nucleic acid based methods of cancer treatment, classified in class 514, subclass 44.

VIII. Claims 42-43, drawn to EDG4 protein inhibition based methods of cancer treatment, classifiable in class 424, subclass 130.1.

IX. Claims 44-45, drawn to methods for cancer diagnosis based on EDG4 protein level determination, classifiable in class 435, subclass 7.1.

X. Claims 53-64, drawn to EDG4-based methods for screening a test molecule and determining treatment efficacy, classified in class 436, subclass 501.

XI. Claims 65-67, drawn to methods for cancer diagnosis based on EDG5 gene copy number, classified in class 435, subclass 6.

XII. Claims 68-73, 78-84, drawn to EDG5 nucleic acid based methods of cancer treatment, classified in class 514, subclass 44.

XIII. Claims 74-75, drawn to EDG5 protein inhibition based methods of cancer treatment, classifiable in class 424, subclass 130.1.

XIV. Claims 76-77, drawn to methods for cancer diagnosis based on EDG5 protein level determination, classifiable in class 435, subclass 7.1.

XV. Claims 85-96, drawn to EDG5-based methods for screening a test molecule and determining treatment efficacy, classified in class 436, subclass 501.

XVI. Claims 97-99, drawn to methods for cancer diagnosis based on EDG8 gene copy number, classified in class 435, subclass 6.

XVII. Claims 100-105,110-116, drawn to EDG8 nucleic acid based methods of cancer treatment, classified in class 514, subclass 44.

XVIII. Claims 106-107, drawn to EDG8 protein inhibition based methods of cancer treatment, classifiable in class 424, subclass 130.1.

XIX. Claims 108-109, drawn to methods for cancer diagnosis based on EDG8 protein level determination, classifiable in class 435, subclass 7.1.

XX. Claims 117-128, drawn to EDG8-based methods for screening a test molecule and determining treatment efficacy, classified in class 436, subclass 501.

XXI. Claims 129-134, drawn to method for cancer treatment using an antibody to S1P, classifiable in class 424, subclass 130.1.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of Groups I-V, VI-X, XI-XV, XVI-XX, and XXI are unrelated. The Groups are drawn to methods comprising five patentably distinct genes: Groups I-V are drawn to products & methods related to SPHK1; Groups VI-X are drawn to EDG4; Groups XI-XV are drawn to EDG5; Groups XVI-XX are drawn to EDG8, and Group XXI is drawn to S1P. The different genes represent patentably distinct subject matter because each gene is composed of a unique polynucleotide sequence, and the respective encoded proteins are each compose of unique polypeptide sequence. Thus the search of any one gene or protein is not coextensive with the search for any other gene or protein, and a reference against one would not be a reference against any other.

For clarity of the further restriction analysis, the Groups of inventions I-XXI will be dealt with as Sets of Groups as follows:

Set 1: Groups I, VI, XI, and XVI (nucleic acid based cancer detection)
Set 2: Groups II, VII, XII, and XVII (nucleic acid based cancer treatment)
Set 3: Groups III, VIII, XIII, XVIII, and XXI (protein based cancer treatment)
Set 4: Groups IV, IX, XIV, and XIX (protein based cancer diagnosis)
Set 5: Groups V, X, XV, and XX (screening and testing methods)

Applicant is reminded that election of a **single Group** is required.

3. Inventions of Sets 1 and 4 (cancer diagnosis methods) are not related to Sets 2 and 3 (cancer treatment methods). Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case the diagnosis methods of Sets 1 and 4 neither recite nor require the treatment methods of Sets 2 and 3. Additionally, the methods have different effects: the diagnosis methods of Sets 1 and 4 determine the presence of illness, whereas the treatment methods of Sets 2 and 3 ameliorate the disease.

4. Inventions of Sets 1 and 2 (nucleic acid based methods) are not related to Sets 3 and 4 (protein based methods). Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case the nucleic acid based methods of Sets 1 and 2 neither recite nor require the protein based methods of Sets 3 and 4. Additionally, the methods have different modes of operation: the nucleic acid based methods of Sets 1 and 2 utilize polynucleotide sequences for

disease diagnosis and treatment, whereas the protein based methods of Sets 3 and 4 utilize polypeptides for disease diagnosis and treatment. Polynucleotides and polypeptides are patentably distinct in structure and physiochemical properties. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. Although the polynucleotides and polypeptides are related, as the claimed polynucleotide is asserted to encode the claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities.

5. Inventions of Set 5 are unrelated to the inventions of Seta 1-4. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the screening and testing methods of Set 5 are neither recited nor required for the diagnosis or treatment methods of Sets 1-4. Additionally the inventions have different goals: the inventions of Set 5 comprise methods to evaluate compounds for activity or therapy regimens for efficacy, whereas the diagnosis methods of Sets 1 and 4 determine the presence of illness, and the treatment methods of Sets 2 and 3 ameliorate the disease.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-XXI require different searches that are not coextensive, examination of these claims would pose a serious

burden on the examiner and therefore restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen Kapushoc
Art Unit 1634

4/17/06
JULIET C. SWITZER
PRIMARY EXAMINER